Brief of Amici Curiae in Support of Defendants' Motion for Judgment on the Pleadings

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SUPERIOR COURT OF THE STATE OF CALIFORNIA
COUNTY OF ALAMEDA

PEOPLE'S ADVOCATE, et al., Plaintiffs, v.	CASE NOS. HG05206766 & 05AS02927 Assigned for All Purposes to Judge Bonnie Lewman Sabraw – Dept. 512 **BRIEF OF AMICI CURIAE IN SUPPORT OF DEFENDANTS' MOTION FOR JUDGMENT ON THE PLEADINGS**

INDEPENDENT CITIZENS' OVERSIGHT COMMITTEE, et al., Defendants.	Date: November 17, 2005 Time: 9:00 a.m. Date of Filing: April 6, 2005
CALIFORNIA FAMILY BIOETHICS COUNCIL, LLC, Plaintiff, v.	
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE, et al., Defendants.	

I. INTRODUCTION

Stem cell research holds promise, over time, not only to transform the study and practice of medicine, but also potentially to transform the lives of countless children and adult sufferers of debilitating and fatal conditions such as spinal cord injury, stroke, burns, brain tumors, heart disease, diabetes, osteoarthritis, and rheumatoid arthritis, Alzheimer's diseases, Parkinson's disease, multiple sclerosis, cystic fibrosis, amyotrophic lateral sclerosis ("Lou Gehrig's Disease"), and liver or pancreatic diseases. Recent experience with the politicization of stem cell research, however, has shown the importance of insulating individual research funding decisions from politics in order to realize fully the potential of regenerative medicine. Proposition 71, the California Stem Cell Research and Cures Act (the Act), established the California Institute for Regenerative Medicine (CIRM) and the Independent Citizens Oversight Committee (ICOC), which governs the Institute, with these very goals in mind.

In establishing the structural and procedural mechanisms through which $3 billion in stem cell research funds will be allocated, Proposition 71 draws on the well-established and enormously successful process through which medical research has traditionally been funded at the federal level by the National Institutes of Health (NIH). The funding process utilized by the NIH relies heavily on peer review and informed public participation to assess the scientific merit of competing research proposals, while limiting the influence of politics in individual funding decisions. Proposition 71 establishes a funding process that parallels the NIH process, and is designed to produce the same benefits. This approach to public funding of needed medical research has a long, respected, and successful history in this country, and will ensure that taxpayer funds are put to their highest and best use.

II. INTEREST OF THE AMICI CURIAE

As both potential recipients of funds authorized by Proposition 71 and as organizations dedicated to the treatment of diseases and injuries that might be affected by stem cell research, amici have a strong interest in ensuring that California's expenditure of $3 billion on stem cell research is, as the voters intended, used wisely. Amici believe that basing funding decisions on scientific merit and recognized public health needs will provide the best opportunity to realize the potential of regenerative medicine. Amici strongly support Proposition 71 because, by predicating funding decisions on peer review and informed public input, the Act ensures that stem cell research funds will be put to their highest and best use in improving public health.

Amici include many of the leading private research institutions in California as well as many of the premier organizations supporting the development of new and innovative treatments and prevention strategies for some of the world's most debilitating diseases and injuries.[1] Those amici engaged in scientific research, like other scientific institutions in this country, have benefited from public financial support, and in particular from funding through the NIH. Funding decisions at the NIH rely heavily on the peer review process, a process that aims to review proposals both for scientific excellence and for consistency with the national research priorities established by Congress.

Amici include individuals and institutions who have thus had substantial experience with the use of peer review and informed public participation in funding scientific research to promote public health. Amici are uniquely positioned to explain the importance and significance of such processes for the development of medical research in California and, more importantly, the development of practical medical solutions.

III. BACKGROUND

A. The Role of Peer Review in Government Funding of Scientific Research

The United States is a world leader in the advancement of medical knowledge. The reasons for that extraordinary success are many, but chief among them has been the federal government's funding of high caliber biomedical research. In the United States, decisions concerning government funding of research proposals have largely been separated from politics.[2] That separation has been achieved by a system that allows political input when establishing broad policy goals, followed by scientific decision-making through the peer review process to determine

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[1] Some amici have officers or employees who also serve on the ICOC.
[2] Tom Abate, What's the Verdict on Peer Review? 21st Century, Volume 1 (No. 1), Spring 1995, Columbia University; GAO Report, Peer Review Practices at Federal Science Agencies Vary, at 1 (March 1999).

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which specific proposals should be funded to achieve those goals. Peer review ensures that the quality of research proposals is judged by scientific merit and by the likelihood that the research proposal will achieve the goal of improving public health.

Although numerous state and federal agencies employ similar methods, the peer review process is particularly well established at the NIH, which allocates approximately $28 billion in federal research funding annually.[3] Each of the institutes and centers within the NIH follows slightly different procedures, but the funding process generally involves two steps.[4] First, a working group of scientists in the relevant field evaluates the scientific and technical merits of each grant application. These scientific "peers" are highly respected, have the appropriate scientific expertise and breadth of knowledge, and are committed to contributing fair, impartial, and high quality reviews. Conflicts of interest are identified, and established processes prevent reviewers from influencing the outcome of applications as to which they may have a potential conflict. Each research proposal is evaluated for its significance, approach, innovation, and the likelihood that the work can be accomplished, as measured by the research accomplishments of the investigator and the environment in which the work will be undertaken.

Second, within each institute, an advisory council of scientists and informed lay citizens considers the recommendations of the peer review process in light of the institute's broad goals, priorities, and available funds. The councils confer with the director of the institute or center and make recommendations on matters of policy and research emphasis. Occasionally an institute director – because of a greater awareness of research priorities based on discussions with patients, scientists, members of the Administration, and the public – may seek to fund a grant with a relatively low rating. The institute director discusses these decisions with the council, which

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[3] See The NIH Almanac—Appropriations, Section 2 (June 30, 2005), http://www.nih.gov/about/almanac/appropriations/part2.htm (reporting NIH's receipt of $27,887,512,000 in Fiscal Year 2004).
[4] See generally NIH, Setting Research Priorities at the National Institutes of Health, http://www.nih.gov/about/researchplanning.htm [hereinafter NIH Research Priorities].

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must approve these decisions before the director may fund them.[5] The vast majority of grants, however, are funded based on peer review.[6] Accordingly, in practice, the assessments made through the peer review process and councils effectively determine which research proposals will receive funding.

The processes followed by the NIH are based on the recognition that scientific peer review is one of the most important mechanisms for promoting the advancement of scientific knowledge and the achievement of public scientific goals. The purpose of peer review in these circumstances is two-fold: (i) to promote and fund those proposals with the most scientific merit or promise through review by scientists with the appropriate knowledge and experience; and (ii) to insulate such assessments from politics as much as possible.[7]

B. Political Influences in Funding for Embryonic Stem Cell Research

Given the diverse views held in our society about the moral and legal status of embryos, it is perhaps not surprising that embryonic stem cell research has met with divergent views and political disagreement. For example, on August 9, 2001, President Bush decided to preclude federal funding for human embryonic stem cell research unless the research involves one of a

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[5] See NIH Research Priorities, supra note 4; Second-Level Review Is a Smaller Hurdle, Grant

Application Basics, National Institute of Allergy and Infectious Diseases, http://www.niaid.nih.gov/ncn/grants/basics/basics_g1.htm.

[6] See How Funding Is Decided: How NIAID Determines Which Applications to Fund, Grant Application Basics, National Institute of Allergy and Infectious Diseases, http://www.niaid.nih.gov/ncn/grants/basics/basics_g4.htm ("After our advisory Council gives its en bloc approval, we fund all grants whose percentiles or priority scores fall within a payline."); see also NIH Research Priorities, supra note 4 ("funding is usually determined by the scientific merit of research applications").

[7] See American Institute of Biological Sciences, Position Statement: Scientific Peer Review in Policy Making, July 15, 2004 ("Scientific peer review should be insulated from politics as much as possible. Oversight of scientific peer review should be vested in scientists and science managers within the agencies. This adds assurance that the composition of panels is not being unduly influenced by politics and constitutes a representative subset of the scientists most competent to review and assess the topic. The agencies must be trusted to perform the task of constituting and overseeing fair and independent scientific peer review efforts, without interference from political entities") (http://www.aibs.org/position-statements/20040715_position_statem.html).

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small number of cell lines existing on that date.[8] While some basic research can be accomplished with existing lines, nearly all scientists agree that new stem cell lines are essential to efficiently advance the scientific and therapeutic potential of regenerative medicine.[9] The federal directive does not prevent non-federally funded development of new stem cell lines, and some non-profit organizations and corporations have pursued this research.[10] But these sources of funding are insufficient without public funding, which the Institute of Medicine has called the "wellspring of medical breakthroughs."[11] Similarly, in 2002 and 2003, the United States House of Representatives passed a bill that would have criminalized somatic cell nuclear transfer, a critical aspect of stem cell research.[12] While this bill never received consideration on the floor of the Senate, it nonetheless sent an intimidating message.[13]

A lack of stable, sufficient funds for research into embryonic stem cell therapies deters young researchers from choosing to pursue a career in this field,[14] and prevents institutions from dedicating substantial facilities to the field.[15] In addition, as the Institute of Medicine has stated:

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[8] See Fact Sheet, Embryonic Stem Cell Research, The White House (Aug. 9, 2001), http://www.whitehouse.gov/news/releases/2001/08/20010809-1.html (describing President Bush's stem cell policy).

[9] Among other reasons, new cell lines are required because federally approved cell lines were cultured in the presence of animal cells or serum, which may contain viruses and other infectious agents not normally found in humans. In addition, stem cell lines tend to change over time, becoming increasingly distant from native human tissues. See Committee on the Biological and Biomedical Applications of Stem Cell Research, Institute of Medicine, Stem Cells and the Future of Regenerative Medicine, 3, 33 (2002), http://www.nap.edu/books/0309076307/html [hereinafter IOM Recommendation] (adding that "while there is much that can be learned using existing stem cell lines if they are widely available for research, such concerns necessitate . . . the development of new stem cell lines in the future").

[10] For example, Geron Corp. claims to have derived the first human embryonic stem cell line without direct exposure to animal-sourced products. See Press Release, Geron Corp., Geron Provides Update on Human Embryonic Stem Cell Programs at International Society for Stem Cell Research Annual Meeting (June 23, 2005), http://ir.geron.com/phoenix.zhtml?c=67323&p=irol-news&nyo=0.

[11] IOM Recommendations, supra note 9, at 3.

[12] H.R. 2505, 107th Cong. § 2 (2002); H.R. 534, 108th Cong. § 2 (2003).

[13] A similar bill is currently pending in the United States Senate. S. 658, 109th Cong. (2005).

[14] Insufficient funding in a "young field such as stem-cell research [makes it] difficult . . . to gather enough preliminary data to make a case for serious study" and obtain grants. See Peter Aldhous, News Feature: After the Gold Rush, 434 Nature 694, 696 (2005). CIRM plans to provide "seed" money to attract new researchers to the field. Id.

[15] Federal dollars may not be used to support any research on stem cell lines created after August

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> [P]ublic funding offers greater opportunities for regulatory

> oversight and public scrutiny of stem cell research. Stem cell research that is publicly funded and conducted under established standards of open scientific exchange, peer review, and public oversight offers the most efficient and responsible means of fulfilling the promise of stem cells to meet the need for regenerative medical therapies.[16]

C. Proposition 71

Proposition 71 was specifically designed to redress the restrictions on federal funding for human embryonic stem cell research. The Act authorizes expenditure of $300 million per year for 10 years for stem cell research, filling the gap in federal funding for what is, for millions of patients and their families, the most promising area of medical research of our time.[17]

The Act establishes a 29-member governing board, the ICOC, to make final decisions on how the research funds authorized by the Act should be spent. Twenty-seven of the ICOC's members are appointed directly by state officials, including the Governor, Lieutenant Governor, Treasurer, Controller, the Speaker of the Assembly, the President pro tempore of the Senate, and the Chancellors of the five University of California campuses with medical schools. These 27 appointed members then pick a chair and vice-chair from lists of nominees provided by the Governor, Lieutenant Governor, Treasurer, and Controller. The ICOC's members serve fixed six- or eight-year terms.

9, 2001, so researchers must ensure that projects funded by Proposition 71 are strictly separated from projects involving federal grants. For example, the Stanford Institute for Cancer/Stem Cell Biology has initially planned to separate California-funded stem cell research by requesting grants to remodel or construct new facilities. See 5 Questions: Longaker on Stem Cell Research, Stan. Rep., April 6, 2005, at 7, http://news-service.stanford.edu/news/2005/april6.

[16] IOM Recommendations, supra note 9, at 3; see also id. at 52–54 (adding that public funding fosters stringent peer review); Saira Moini and Bill Kearney, Science & Society: The Promise and Perplexities of Stem Cells, The National Academies InFocus, Fall/Winter 2001, at 26, http://www.infocusmagazine.org/1.2/science_society.html ("Without government funding of basic research on stem cells, progress toward medical therapies is likely to be hindered. Private industry may be reluctant to fund research that could take many years and with no guarantee of the results yielding profitable applications.").

[17] See IOM Recommendation, supra note 9, at 34-36 (outlining evidence supporting potential use of human embryonic stem cells in regenerative medicine); Fred H. Gage and Inder M. Verma, Introduction: Stem Cells at the Dawn of the 21st Century, 100 Proc. of the Nat. Acad. Sci. 11817, 11817 (2003) (describing potential cures); Stem Cell Information, Frequently Asked Questions, National Institutes of Health, http://stemcells.nih.gov/info/faqs.asp#whatare.

Proposition 71 requires that the ICOC's membership include informed public and private individuals with a diverse range of backgrounds and viewpoints especially relevant to stem cell research. Five ICOC members are representatives of the University of California medical schools; four are representatives of private California universities with demonstrated leadership in stem cell research; four are representatives of California nonprofit academic or research institutions that have demonstrated leadership in stem cell research; four are representatives of California life science companies with experience in implementing successful medical therapies; and ten are advocates for people suffering from diseases and conditions believed likely to benefit from therapies and prevention strategies developed from stem cell research.

The practical wisdom of these provisions is manifest in the ICOC's current membership, which includes individuals with long and distinguished careers in the relevant sciences and medical specialties. The ICOC includes several members of the distinguished National Academy of Sciences[18] and Institute of Medicine,[19] Nobel Prize winner David Baltimore, former U.S. Food and Drug Administration commissioner David Kessler, and Ed Penhoet, biochemist and cofounder of Chiron, the developer of therapies for diseases such as Hepatitis B. In addition, several prominent patient advocates serve on the ICOC, including, for example: Sherry Lansing, chair of Stop Cancer as well as the former chair of Paramount Pictures; Joan Samuelson, founder and president of the Parkinson's Action Network; and Oswald Steward, Ph.D., chair and director of the Reeve-Irvine Research Center at the University of California, Irvine.[20]

IV. ARGUMENT

Plaintiffs challenge Proposition 71's constitutionality, inter alia, on the ground that the ICOC is "too independent." Although the precise basis of this argument is unclear, plaintiffs

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[18] David Baltimore and Robert Birgeneau. See Members, National Academy of Sciences (2005), http://www.nasonline.org (follow "Members" hyperlink).
[19] David Baltimore, Brian Henderson, Edward Holmes, David Kessler, Ed Penhoet, and Philip Pizzo. See Membership, Institute of Medicine of the National Academies (June 6, 2005), http://www.iom.edu/About-IOM/Membership.aspx (follow "2005 IOM Public Directory," then download PDF directory).
[20] See ICOC Members List, ICOC Info, California Institute for Regenerative Medicine, http://www.cirm.ca.gov/icoc.

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appear to contend that state officials do not exert "sufficient control" over the ICOC's members to make the ICOC an entity "under the exclusive management and control of the State" pursuant to Article XVI, Section 3 of the California Constitution.

For several reasons, this argument is without merit. As the Attorney General points out in his moving papers, Proposition 71 itself amends the California Constitution by adding Article XXXV, Section 6. The amendment provides that, notwithstanding any other provision of the Constitution, CIRM (of which the ICOC is the governing body) is established in state government and may spend state funds. The voters thus made sure there was no constitutional impediment to CIRM spending state funds for regenerative medicine. Moreover, all of the ICOC's members are appointed or nominated by state elected officials or state officials who hold public office, and the Act provides both adequate guidance on the manner in which taxpayer funds are to be spent and adequate external controls to ensure that the funds are spent within the limitations specified in the Act.

The details of issues relating to constitutional and statutory interpretation we leave to the Attorney General. Amici submit this brief to explain why the structure and composition of the ICOC will help ensure that the $3 billion in stem cell research funds authorized by Proposition 71 are expended in the manner the voters desired: to develop meaningful treatment, prevention strategies, and cures for serious diseases afflicting millions of people.

A. The Structure and Composition of the ICOC Ensure That Funding Decisions Will Be Made Based on Scientific Merit.

The ICOC's structure and composition are carefully designed to produce the same benefits as the peer review process used by the NIH. To ensure that stem cell research funds are spent in a scientifically sensible manner consistent with Proposition 71's mandate, the Act establishes a two-step process similar to that used at the NIH.

First, all proposals are subject to exacting peer review by working groups that include both nationally recognized scientists and representatives of advocacy groups.[21] By virtue of their

21 Section 125290.60(b) (describing Scientific and Medical Research Funding Working Group's background and experience, these individuals are particularly well equipped to evaluate significant issues: whether the proposal is original and innovative; whether the proposal is scientifically plausible and realistic; whether the proposal's design is adequately developed; and whether the proposed investigators have the necessary facilities and expertise to conduct the proposed study.[22]

Second, recommendations by the working groups (including certain dissenting opinions) are then evaluated by the 29-member ICOC, which has final authority to decide which research proposals will be funded. As noted above, the ICOC itself is composed of individuals who are extraordinarily well qualified to make the scientific and health-policy judgments necessary to decide whether to accept or reject the recommendations made by the working groups. Decisions about which research proposals warrant funding are thus made by those with the knowledge and expertise necessary to make informed assessments of both the scientific merit of a proposal and the extent to which a proposal is likely to contribute to the search for meaningful prevention strategies, cures, and treatments.

Plaintiffs fault the ICOC because it "has no members who are elected or public officials." (Complaint ¶ 12.) But the long history of public funding of medical research has demonstrated the wisdom of using peer reviewers and informed public participants rather than elected officials to assess the scientific merit of a given proposal. Rather than establishing a committee composed of the Governor, Lieutenant Governor, Treasurer, and Controller to make final funding decisions, Proposition 71 sensibly requires these elected officials to appoint to the ICOC members whose background and experience render them qualified to evaluate the scientific merits of competing research proposals.

Moreover, nothing in the California Constitution precludes the State from allocating scientific research funds through a process that insulates individual funding decisions from direct

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role in peer review of grant applications and recommendation of awards to ICOC).
[22] NIH's five review criteria provide an idea of how peer review generally operates. See NIH Has Five Review Criteria, Grant Application Basics, National Institute of Allergy and Infectious Diseases, http://www.niaid.nih.gov/ncn/grants/basics/basics_b3.htm.

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political influence. By establishing a governing body whose members serve for fixed terms and cannot be removed at will by the officials who appoint them, Proposition 71 allows members of the ICOC to make assessments governed solely by their view of the objective merits of a particular proposal, without concern for political expedience. The Act thereby ensures that taxpayer funds will be allocated to those research proposals holding the most scientific and therapeutic promise, in a manner similar to the process utilized with great success at the NIH. In this respect, Proposition 71 is no different from an act establishing any other government agency dealing with scientific or other highly specialized matters.[23]

B. The ICOC's Structure Helps Ensure Long Term Stability of Funding.

The ICOC's structure also provides important stability in an area where research and development require a long term commitment. As noted above, the federal government has not been willing to provide that commitment in the area of embryonic stem cell research. Although congressional attempts are underway to relax some of the restrictions currently in place, the prospects for ultimate passage remain uncertain and a veto has been threatened as to any such legislation. Given the highly politicized nature of the subject, embryonic stem cell research remains especially vulnerable to shifts in political winds and the political fortunes of particular officials and candidates.

Further, while regenerative medicine is one of the most promising fronts of medicine today, research and development of practical medical treatments and cures will almost certainly take many years.[24] Any uncertainty as to whether a reliable source of funding will exist in future years would make it extremely difficult to attract young and innovative researchers to careers in an otherwise promising new field.[25] No one wants to start down a new path of research that

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[23] See, e.g., California Medical Assistance Commission (Welf. & Inst. Code § 14165.2), State Commission on Teacher Credentialing (Ed. Code § 44213), Student Aid Commission (Ed. Code § 65911), and Fair Employment and Housing Commission (Govt. Code § 12903).
[24] See Ruth R. Faden and John D. Gearhart, Facts on Stem Cells, Washington Post, August 23, 2004, at A15; Moini and Kearney, supra note 15, at 26.
[25] See supra note 14.

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shows great promise only to have funding for that research thrown into doubt every election cycle.

Proposition 71 addresses this problem first by providing a reliable source of long term funding, roughly $300 million annually over a period of 10 years, and second by providing fixed terms of office for ICOC members. Because the ICOC's members serve for fixed six- or eightyear terms and are not subject to removal at the whim of the officials who appoint them, their funding decisions cannot be reversed by elected officials who do not agree with the goals of Proposition 71. Thus, researchers whose proposals are selected for funding can be assured that an elected official's displeasure with a particular funding decision will not result in funding being revoked the following year.

C. The ICOC's Composition Ensures That a Wide Range of Scientific Viewpoints and Informed Public Perspectives Will Be Represented.

Finally, by specifying criteria for the composition of the ICOC, Proposition 71 ensures that funding decisions will reflect input from a wide variety of scientific and disease advocacy viewpoints. The Act mandates that the ICOC include representatives of the five University of California campuses with medical schools, other leading private or public universities in California, non-profit academic and medical research institutions, and companies with expertise in developing medical therapies. In addition, the Act requires the ICOC to include representatives of organizations concerned with ten specified diseases likely to benefit from stem cell research: spinal cord injury; Alzheimer's disease; type II diabetes; multiple sclerosis or amyotrophic lateral sclerosis; type I diabetes; heart disease; cancer; Parkinson's disease; HIV/AIDS; and mental health problems.[26] This diverse range of viewpoints and backgrounds ensures that funding

decisions will not be dominated by any one narrow perspective and that knowledge will not be pursued solely for the sake of knowledge.

The presence of the disease advocacy representatives has the additional benefit of enhancing the role that non-scientists play in making funding decisions. At the NIH, ordinary

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26 Section 125290.20(a)(3).

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citizens participate in the funding process through service on an Institute's Council of Public Representatives. The ICOC's composition guarantees an even broader community perspective, and brings that perspective directly into the decision-making process. Collectively, the disease advocacy representatives provide informed public input into decisions about how stem cell research projects are best prioritized. That function is bolstered by other provisions of the Act, which authorize issuance of majority and minority reports to the public when significant disagreement exists within the peer review advisory process on funding decisions, as well as public hearings to air those disagreements.[27]

V. CONCLUSION

Proposition 71 establishes a constitutionally valid process for allocating the $3 billion in stem cell research funds authorized by California's voters. Proposition 71's dedication to a peer review, merits-based decision-making process will help ensure that the public's money is spent wisely, on those research programs most likely to bear meaningful fruit and to bear it soon. Amici agree with Defendants that nothing in our Constitution precludes the people from adopting such a

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27 Section 125290.50(d).

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system for funding scientific research. Accordingly, Defendants' motion for a Judgment on the Pleadings should be granted.

DATED: October 12, 2005	MUNGER, TOLLES & OLSON LLP O'MALLEY M. MILLER MICHAEL R. DOYEN MARK H. EPSTEIN PAUL J. WATFORD
	By: _____ Attorneys for AMICI CURIAE, California Institute of Technology, Keck Graduate Institute, The Board of Trustees of the Leland Stanford Junior University, University of Southern California, Burnham Institute for Medical Research, Cedars-Sinai Medical Center, Children's Hospital Los Angeles, Children's Hospital & Research Center at Oakland, City of Hope, Salk Institute for Biological Studies, Alliance for Aging Research, Alliance for Stem Cell Research, ALS Association, Alzheimer's Association California Council, Cancer Research & Prevention Foundation, Christopher Reeve Foundation, Cystic Fibrosis Research, Inc., Elizabeth Glaser Pediatric AIDS Foundation, Juvenile Diabetes Research Foundation, The Leukemia & Lymphoma Society, Michael J. Fox Foundation for Parkinson's Research, National Brain Tumor Foundation, National Multiple Sclerosis Society, Parkinson's Action Network, San Francisco AIDS Foundation, Southern California Biomedical Council, Dr. Paul Berg, Nobel Laureate

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